Samus Therapeutics Announces First Patient Dosed in Phase 1b Study of Icapamespib in Recurrent Malignant Glioma

Boston, MA, January 5, 2022 – Samus Therapeutics, Inc. ("Samus Therapeutics" or the "Company"), a privately held, Boston-based biopharmaceutical company with a novel approach to protein degradation and restoration of normal cellular functions to treat cancer and central nervous system (CNS) diseases, today announced the first patient was dosed in the multicenter Phase 1b study of icapamespib in patients with recurrent malignant glioma.

Over 24,000 patients are diagnosed with primary brain tumors (non-metastatic) in the U.S. per year and of these approximately half are classified as glioblastomas, a type of fast-growing high grade glioma[1]. The five-year survival rate for patients >55 years old is particularly poor (6-15%)[1].

"Patients with recurrent malignant glioma face a poor prognosis. Currently, standard treatments are sub-optimal and there is an urgent need for the development of new promising therapeutics," said Howard Colman, MD, PhD, Co-Leader of the Center for Neurologic Cancers and Co-Leader of the Experimental Therapeutics Program at the Huntsman Cancer Institute at the University of Utah, and principal investigator of the Phase 1b study. "I look forward to investigating a therapy which may help address this significant unmet patient need."

The Phase 1b trial consists of two stages. The first stage is currently recruiting patients and will evaluate the safety, tolerability and pharmacokinetics of icapamespib. This dose escalation stage is designed to define a recommended Phase 2 dose (RP2D). The second stage, dose expansion, will confirm the safety and tolerability of the RP2D.

Icapamespib (PU-AD, PU-HZ151) is an oral small molecule that crosses the blood brain barrier and is designed to inhibit epichaperomes, protein complexes which support cancer growth. In a recently published article, Bolaender et al[2] demonstrated in preclinical studies that glioblastomas express high levels of epichaperomes and that treatment response to icapamespib directly correlates with epichaperome expression levels. In ex-vivo studies using patients' surgical explants from tumors resistant to temozolomide and bevacizumab, drugs routinely utilized to treat malignant glioma, inhibition of epichaperomes with icapamespib initiated aberrant protein degradation and induced cancer cell death.

"We are excited to test the novel approach of epichaperome inhibition with icapamespib and to evaluate how it can benefit patients with recurrent malignant glioma," said Dick Bagley, Chief Executive Officer of Samus Therapeutics.

References

[1] American Cancer Society, https://www.cancer.org/cancer/brain-spinal-cord-tumors-adults/about/key-statistics.html

[2] Bolaender A. et al. NATURE COMMUNICATIONS 2021;12:4669

About Samus Therapeutics

Samus Therapeutics, Inc. is a privately held, Boston-based biotechnology company focused on addressing areas of high unmet medical need in cancer and neurodegenerative diseases through a novel approach to protein degradation and restoration of normal cellular pathways. Samus has a broad proprietary technology platform with two clinical-stage lead small molecules (zelavespib and icapamespib) targeting recurrent malignant glioma, myeloproliferative neoplasm, and neurodegenerative disorders including ALS and Alzheimer's Disease.

This press release contains certain forward-looking information about Samus Therapeutics, Inc. that is intended to be covered by the safe harbor for "forward-looking statements" provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," "forecasts," and "believes." These statements include, but are not limited to, statements regarding the progress, timing and results of preclinical and clinical trials involving the Company's drug candidates, and the progress of the Company's research and development programs. All such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied by, the forward-looking statements. These risks and uncertainties include, but are not limited to whether any of our therapeutic candidates will advance further in the preclinical or clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies, whether our products will be successfully marketed if approved; the strength and enforceability of our intellectual property rights; and competition from other pharmaceutical and biotechnology companies. While Samus Therapeutics may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to update or revise any forward-looking-statements contained in this press release whether as a result of new information or future events, except as may be required by law.

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